



JC02 Rec'd PCT/PTO 01 SEP 2005

PCT

PATENT

Docket No.: 20747/280 (ARDBW/P29385US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Rodney William Kelly

Serial No. : 10/532,291

Cnfrm. No. : To Be Assigned

Filed : October 21, 2003

For : COMPOSITIONS FOR THE TREATMENT OF
AUTOIMMUNE DISORDERS

Examiner:
To Be Assigned

Art Unit:
To Be Assigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

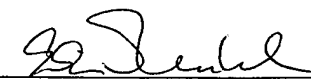
Pursuant to 37 CFR §§ 1.97-1.98, applicant hereby brings to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO-1449 form. Reference Nos. 7, 9, 12, 21, 28, 64-65, 93, and 111 were cited in a International Search Report (copy enclosed) for the corresponding PCT patent application. Reference No. 16 was cited in search report from the United Kingdom (copy enclosed).

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. Patents (i.e., Reference Cite Nos. 1-13) are not enclosed. Copies of all other listed references (i.e., Reference Cite Nos. 14-120) are enclosed herewith.

Pursuant to 37 CFR § 1.97(b)(3), no fee is required. If additional fees are required, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 14-1138.

Respectfully submitted,

Date: August 29, 2005


Edwin V. Merkel
Registration No. 40,087

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1128
Facsimile: (585) 263-1600

R872285.1

Certificate of Mailing - 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents P.O. Box 1450
Alexandria, VA 22313-1450, on the date below.

Date 8/30/05 
Mary Burke

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	1	US-4,034,087	07/05/1977	Voorhees	
	2	US-4,127,612	11/28/1978	Kluender et al.	
	3	US-5,229,496	07/20/1993	Deeley et al.	
	4	US-5,391,485	02/21/1995	Deeley et al.	
	5	US-5,393,870	02/28/1995	Deeley et al.	
	6	US-5,602,007	02/11/1997	Dunn et al.	
	7	US-5,891,432	04/06/1999	Hoo	
	8	US-5,908,829	06/01/1999	Kelly	
	9	US-6,010,905	01/04/2000	Cohen et al.	
	10	US-6,127,378	10/03/2000	Gutterer	
	11	US-6,280,718 B1	08/28/2001	Kaufman et al.	
	12	US-6,458,585 B1	10/01/2002	Vachula et al.	
	13	US-6,458,589 B1	10/01/2002	Rambhatla et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	14	DE 100 64 991 A1	06/27/2002	Volker		X
	15	DE 24 31 558	01/23/1975	Kuehl jun et al.		X
	16	EP 0 269 017 B1	07/29/1992	Zimmermann et al.		
	17	EP 1 097 922 A1	05/09/2001	Maruyama et al.		
	18	EP 1 114 816 A1	07/11/2001	Maruyama et al.		
	19	EP 1 199 074 A1	04/24/2002	Moulon et al.		
	20	JP 10-29942	02/03/1998	Tadahiro et al.		X
	21	WO 00/64260	11/02/2000	Benoit et al.		
	22	WO 01/17479 A2	03/15/2001	Neal		
	23	WO 02/092064 A2	11/21/2002	Kelly		
	24	WO 91/06571	05/16/1991	Gefter et al.		
	25	WO 92/08474	05/29/1992	Kay et al.		
	26	WO 94/24281	10/27/1994	Garman et al.		
	27	WO 96/30022	10/03/1996	Desai et al.		
	28	WO 99/12563	03/18/1999	Berzofsky et al.		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at 222.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	2	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	29	"Leukine®," Package Insert, Approved Text (February 1998)	
	30	ALGHAFEER & SIGAL, "Rheumatic Manifestations of Gastrointestinal Diseases," <i>Bulletin on the Rheumatic Diseases</i> 51(2):1-7 (Retrieved from the internet at http://www.arthritis.org/research/bulletin/vol51no2/51_2_printable.asp) (March 10, 2005)	
	31	ASANUMA et al., "Successful Treatment of Interstitial Pneumonia with Lipo-PGE1 and Pentoxifylline in a Patient with Dermatomyositis," <i>Ryumachi</i> 37(5):719-726 (1997) (English language abstract only)	
	32	ASSEMAN et al., "Interleukin 10 is a Growth Factor for a Population of Regulatory T Cells," <i>Gut</i> 42(2):157-158 (1998)	
	33	AITKEN et al., "Significance of Intracellular Calcium and Cyclic Adenosine 3',5'-monophosphate in the Mechanisms by Which Prostaglandins Influence Human Sperm Function," <i>J. Reprod. Fert.</i> 77:451-462 (1986)	
	34	BELL, J., "Transplantation: Privileged Beginnings," <i>Nature Reviews Immunology</i> 2:75 (2002)	
	35	BERENDS et al., "Inhibitions of PAF-Induced Expression of CD11b and Shedding of L-Selectin on Human Neutrophils and Eosinophils by the Type IV Selective PDE Inhibitor, Rolipram," <i>Eur. Respir. J.</i> 10:1000-1007 (1997)	
	36	BRAUN et al., "Cholera Toxin Suppresses Interleukin (IL)-12 Production and IL-12 Receptor β 1 and β 2 Chain Expression," <i>J. Exp. Med.</i> 189(3):541-552 (1999)	
	37	BRODSKY et al., "Forskolin Induces U937 Cell Line Differentiation as a Result of a Sustained cAMP Elevation," <i>Eur. J. Pharmacol.</i> 350(1):121-127 (1998)	
	38	BUCHSEL et al., "Granulocyte Macrophage Colony-Stimulating Factor: Current Practice and Novel Approaches," <i>Clin. J. Oncol. Nurs.</i> 6(4):198-205 (2002)	
	39	BUG et al., "cAMP Analogues Downregulate the Expression of Granulocyte Macrophage Colony-Stimulating Factor (GM-CSF) in Human Bone Marrow Stromal Cells <i>In Vitro</i> ," <i>Mediators of Inflammation</i> 7:195-199 (1998)	
	40	BURZYN et al., "Decrease in cAMP Levels Modulates Adhesion to Fibronectin and Immunostimulatory Ability of Human Dendritic Cells," <i>J. Leukoc. Biol.</i> 72:93-100 (2002)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	3	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	41	CANTRELL et al., "Cloning, Sequence, and Expression of a Human Granulocyte/Macrophage Colony-Stimulating Factor," <i>Proc. Natl. Acad. Sci. USA</i> 82(18):6250-6254 (1985)	
	42	CLAESSEN et al., "Reversal of Mucosal Tolerance by Subcutaneous Administration of Interleukin-12 at the Site of Attempted Sensitization," <i>Immunology</i> 88(3):363-367 (1996)	
	43	CROCKER et al., "Phosphodiesterase Type 4 Inhibitors, But Not Glucocorticoids, Are More Potent in Suppression of Cytokine Secretion by Mononuclear Cells from Atopic Than Nonatopic Donors," <i>J. Allergy Clin. Immunol.</i> 102(5):797-804 (1998)	
	44	DIECKGRAEFE & KORZENIK, "Treatment of Active Crohn's Disease with Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor," <i>The Lancet</i> 360:1478-1480 (2002)	
	45	DONCKIER et al., "IL-12 Prevents Neonatal Induction of Transplantation Tolerance in Mice," <i>Eur. J. Immunol.</i> 28(4):1426-1430 (1998)	
	46	DOUSA, T.P., "Cyclic-3', 5'-Nucleotide Phosphodiesterase Isozymes in Cell Biology and Pathophysiology of the Kidney," <i>Kidney International</i> 55:29-62 (1999)	
	47	DRUKKER et al., "Characterization of the Expression of MHC Proteins in Human Embryonic Stem Cells," <i>Proc. Natl. Acad. Sci. USA</i> 99(15):9864-9869 (2002)	
	48	DUNN et al., "IL-15 Regulation in Human Endometrial Stromal Cells," <i>J. Clin. Endocrinol. Metab.</i> 87(4):1898-1901 (2002)	
	49	ESCOFIER et al., "Effects of Interleukin-10 and Modulators of Cyclic AMP Formation on Endotoxin-Induced Inflammation in Rat Lung," <i>Fundam. Clin. Pharmacol.</i> 13(1):96-101 (1999)	
	50	GASPAR ELSAS et al., "Murine Myeloid Progenitor Responses to GM-CSF and Eosinophil Precursor Responses to IL-5 Represent Distinct Targets for Downmodulation by Prostaglandin E ₂ ," <i>Br. J. Pharmacol.</i> 130(6):1362-1368 (2000)	
	51	GENBANK ACCESSION NO. NM_000758 (2002)	
	52	GOERDT et al., "Other Functions, Other Genes: Alternative Activation of Antigen-Presenting Cells," <i>Immunity</i> 10:137-142 (1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	4	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	53	GROUX et al., "Interleukin-10 Induces a Long-Term Antigen-Specific Anergic State in Human CD4 ⁺ T Cells," <i>J. Exp. Med.</i> 184:19-29 (1996)	
	54	GROUX et al., "A CD4 ⁺ T-Cell Subset Inhibits Antigen-Specific T-Cell Responses and Prevents Colitis," <i>Nature</i> 389:737-742 (1997)	
	55	HAMILTON, J.A., "GM-CSF in Inflammation and Autoimmunity," <i>Trends Immunol.</i> 23(8):403-408 (2002)	
	56	HANCOCK et al., "Recombinant Granulocyte-Macrophage Colony-Stimulating Factor Down-Regulates Expression of IL-2 Receptor on Human Mononuclear Phagocytes by Induction of Prostaglandine," <i>J. Immunol.</i> 140(9):3021-3025 (1988)	
	57	HANIFIN & CHAN, "Monocyte Phosphodiesterase Abnormalities and Dysregulation of Lymphocyte Function in Atopic Dermatitis," <i>J. Invest. Dermatol.</i> 105:84S-88S (1995)	
	58	HANIFIN et al., "Type 4 Phosphodiesterase Inhibitors Have Clinical and <i>In Vitro</i> Anti-Inflammatory Effects in Atopic Dermatitis," <i>Journal of Investigative Dermatology</i> 107:51-56 (1996)	
	59	HARIZI et al., "Cyclooxygenase-2-Issued Prostaglandin E ₂ Enhances the Production of Endogenous IL-10, Which Down-Regulates Dendritic Cell Functions," <i>J. Immunol.</i> 168(5):2255-2263 (2002)	
	60	HASKÓ et al., "Suppression of IL-12 Production by Phosphodiesterase Inhibition in Murine Endotoxemia is IL-10 Independent," <i>Eur. J. Immunol.</i> 28:468-472 (1998)	
	61	HATA et al., "Granulysin Blocks Replication of Varicella-Zoster Virus and Triggers Apoptosis of Infected Cells," <i>Viral Immunol.</i> 14(2):125-133 (2001)	
	62	HAYASHIDA et al., "Antiinflammatory Effects of Colforsin Daropate Hydrochloride, a Novel Water-Soluble Forskolin Derivative," <i>Ann. Thoracic Surgery</i> 71:1931-1938 (2001)	
	63	HOLT et al., "MHC Class II Antigen-Bearing Dendritic Cells in Pulmonary Tissues of the Rat," <i>J. Exp. Med.</i> 167:262-274 (1988)	
	64	ICHIMURA et al., "Differentiation of a Cell Line of Human Cervical Argyrophil Small Cell Carcinoma to Macrophage Lineage Cells," <i>Jpn. J. Cancer Res.</i> 90:523-529 (1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	5	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	65	KALIŃSKI et al., “Dendritic Cells, Obtained from Peripheral Blood Precursors in the Presence of PGE ₂ , Promote Th2 Responses,” <i>Adv. Exp. Med. Biol.</i> 416:363-367 (1997)		
	66	KALIŃSKI et al., “Final Maturation of Dendritic Cells Is Associated with Impaired Responsiveness to IFN-γ and to Bacterial IL-12 Inducers: Decreased Ability of Mature Dendritic Cells to Produce IL-12 During the Interaction with Th Cells,” <i>J. Immunol.</i> 162:3231-3236 (1999)		
	67	KALIŃSKI et al., “Prostaglandin E ₂ Induces the Final Maturation of IL-12-Deficient CD1a ⁺ CD83 ⁺ Dendritic Cells: The Levels of IL-12 Are Determined During the Final Dendritic Cell Maturation and Are Resistant to Further Modulation,” <i>J. Immunol.</i> 161:2804-2809 (1998)		
	68	KAMBAYASHI et al., “Cyclic Nucleotide Phosphodiesterase Type IV Participates in the Regulation of IL-10 and in the Subsequent Inhibition of TNF-α and IL-6 Release by Endotoxin-Stimulated Macrophages,” <i>Journal of Immunology</i> 155:4909-4916 (1995)		
	69	KANAMORI et al., “Migration of Neutrophils from Blood to Tissue: Alteration of Modulatory Effects of Prostanoid on Superoxide Generation in Rabbits and Humans,” <i>Life Science</i> 60(16):1407-1417 (1997)		
	70	KANDA & WATANABE, “Ganglioside GD1a Enhances Immunoglobulin Production by Human Peripheral Blood Mononuclear Cells,” <i>Exp. Hematol.</i> 28(6):672-679 (2000)		
	71	KELLY & CRITCHLEY, “Immunomodulation by Human Seminal Plasma: A Benefit for Spermatozoon and Pathogen?” <i>Human Reproduction</i> 12(10):220-2207 (1997)		
	72	KELLY et al., “Inflammatory Mediators and Endometrial Function—Focus on the Perivascular Cell,” <i>J. Reprod. Immunol.</i> 57(1-2):81-93 (2002)		
	73	KELLY, J., “Shooting for the Moon: Bolstered By a New Research Agenda, Parkinson’s Disease Researchers Aim High,” <i>Neurology Reviews.com</i> 9(7):1-10 (2001)		
	74	KELLY et al., “The Immunosuppressive Contribution of Prostaglandin Components of Human Semen and Their Ability to Elevate Cyclic Adenosine Monophosphate Levels in Peripheral Blood Mononuclear Cells,” <i>J. Reprod. Immunol.</i> 26:31-40 (1994)		
	75	KOELMAN et al., “Correlation Between Oral Sex and a Low Incidence of Preeclampsia: A Role for Soluble HLA in Seminal Fluid?” <i>J. Reproductive Immunol.</i> 46:155-166 (2000)		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	6	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	76	KRENSKY, A.M., "A Novel Antimicrobial Peptide of Cytolytic T Lymphocytes and Natural Killer Cells," <i>Biochem. Pharmacol.</i> 59(4):317-320 (2000)		
	77	LECHNER et al., "Nestin-Positive Progenitor Cells Derived from Adult Human Pancreatic Islets of Langerhans Contain Side Population (SP) Cells Defined by Expression of the ABCG2 (BCRP1) ATP-Binding Cassette Transporter," <i>Biochem. Biophys. Res. Comm.</i> 293:670-674 (2002)		
	78	LEE et al., "Isolation of cDNA for a Human Granulocyte-Macrophage Colony-Stimulating Factor by Functional Expression in Mammalian Cells," <i>Proc. Natl. Acad. Sci. USA</i> 82:4360-4364 (1985)		
	79	LOUIS et al., "Decrease in Systemic Tolerance to Fed Ovalbumin in Indomethacin-Treated Mice," <i>International Archives of Allergy and Immunology</i> 109(1):21-26 (1996)		
	80	MAIER et al., "Unique Molecular Surface Features of <i>in vivo</i> Tolerized T Cells," <i>Proc. Natl. Acad. Sci. USA</i> 95:4499-4503 (1998)		
	81	MAURANO et al., "Intranasal Administration of One Alpha Gliadin Can Downregulate the Immune Response to Whole Gliadin in Mice," <i>Scand. J. Immunol.</i> 53:290-295 (2001)		
	82	MIYATAKE et al., "Structure of the Chromosomal Gene for Granulocyte-Macrophage Colony Stimulating Factor: Comparison of the Mouse and Human Genes," <i>EMBO J.</i> 4(10):2561-2568 (1985)		
	83	MORIUCHI et al., "Synergistic Inhibition of Pannus Tissue Development In Vitro by PGE1 Plus Phosphodiesterase 4 Inhibitors," <i>Arthritis and Rheumatism</i> 41(9):S161 (1998)		
	84	MÜLLER et al., "IL-12 as Mediator and Adjuvant for the Induction of Contact Sensitivity In Vivo," <i>J. Immunol.</i> 155(10):4661-4668 (1995)		
	85	MÜLLER et al., "Subtypes of the Type 4 cAMP Phosphodiesterases: Structure, Regulation and Selective Inhibition," <i>Trends Pharmacol. Sci.</i> 17:294-298 (1996)		
	86	NÉMETH et al., "Amrinone and Theophylline Differentially Regulate Cytokine and Nitric Oxide Production in Endotoxemic Mice," <i>Shock</i> 7(5):371-375 (1997)		
	87	NEWBERRY et al., "Cyclooxygenase-2-Dependent Arachidonic Acid Metabolites Are Essential Modulators of the Intestinal Immune Response to Dietary Antigen," <i>Nature Medicine</i> 5(8):900-906 (1999)		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
Examiner Name	To Be Assigned				
Sheet	7	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	88	NEWBERRY et al., "Spontaneous and Continuous Cyclooxygenase-2-Dependent Prostaglandin E ₂ Production by Stromal Cells in the Murine Small Intestine Lamina Propria: Directing the Tone of the Intestinal Immune Response," <i>J. Immunol.</i> 166(7):4465-4472 (2001)		
	89	NINNEMANN, J.L., "Monocytes and Macrophages," in <i>Prostaglandins, Leukotrienes, and the Immune Response</i> , Chapter 3, pp.34-52 (1988)		
	90	OCHOA et al., "T-Cell Release of Granulysin Contributes to Host Defense in Leprosy," <i>Nature Medicine</i> 7(2):174-179 (2001)		
	91	PALFREYMAN & SOUNESS, "Phosphodiesterase Type IV Inhibitors," <i>Progress in Medicinal Chemistry</i> 33:1-52 (1996)		
	92	PFENDLER & KAWASE et al., "The Potential of Stem Cells," <i>Obstetrical & Gynecology Survey</i> 58(3):197-208 (2003)		
	93	PIQUET-PELLORCE et al., "Prostaglandin E ₂ Potentiates Granulocyte-Macrophage Colony Stimulating Factor-Induced Histamine Synthesis in Bone Marrow Cells: Role of cAMP," <i>Life Sciences</i> 48(25):2377-2385 (1991)		
	94	RIESER et al., "Prostaglandin E ₂ and Tumor Necrosis Factor α Cooperate to Activate Human Dendritic Cells: Synergistic Activation of Interleukin 12 Production," <i>J. Exp. Med.</i> 186(9):1603-1608 (1997)		
	95	RITZ et al., "On the Generation of Allergic Airway Diseases: From GM-CSF to Kyoto," <i>Trends Immunol.</i> 23(8):396-402 (2002)		
	96	ROBERTSON & SHARKEY, "The Role of Semen in Induction of Maternal Immune Tolerance to Pregnancy," <i>Seminars in Immunology</i> 13:243-254 (2001)		
	97	ROBERTSON et al., "Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) Targets Myeloid Leukocytes in the Uterus During the Post-Mating Inflammatory Response in Mice," <i>J. Reproductive Immunology</i> 46:131-154 (2000)		
	98	ROWE et al., "Inability of Histamine to Regulate TNF- α Production by Human Alveolar Macrophages," <i>Am. J. Respir. Cell Mol. Biol.</i> 17:218-226 (1997)		
	99	ROZENGURT et al., "Mitogenic Effect of Prostaglandin E ₁ in Swiss 3T3 Cells: Role of Cyclic AMP," <i>Journal of Cellular Physiology</i> 116:379-384 (1983)		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	8	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	100	RUGTVEIT et al., "Differential Distribution of B7.1 (CD80) and B7.2 (CD86) Costimulatory Molecules on Mucosal Macrophage Subsets in Human Inflammatory Bowel Disease (IBD)," <i>Clin. Exp. Immunol.</i> 110(1):104-113(1997)	
	101	SALMI & JALKANEN et al., "Human Leukocyte Subpopulations from Inflamed Gut Bind to Joint Vasculature Using Distinct Sets of Adhesion Molecules," <i>Journal of Immunology</i> 166(7):4650-4657 (2001)	
	102	SANTAMARIA et al., "Rolipram Inhibits Staphylococcal Enterotoxin B-Mediated Induction of the Human Skin-Homing Receptor on T Lymphocytes," <i>J. Invest. Dermatol.</i> 113:82-89 (1999)	
	103	SCHEUER et al., "Interference with Tolerance Induction <i>in Vivo</i> by Inhibitors of Prostaglandin Synthesis," <i>Cellular Immunology</i> 104(2):409-418 (1987)	
	104	SCHWACHA et al., "Cyclooxygenase 2-Mediated Suppression of Macrophage Interleukin-12 Production After Thermal Injury," <i>Am. J. Physiol. Cell Physiol.</i> 282(2):263-270 (2002)	
	105	SELDON & GIEMBYCZ et al., "Suppression of Granulocyte/Macrophage Colony-Stimulating Factor Release from Human Monocytes by Cyclic AMP-Elevating Drugs: Role of Interleukin-10," <i>Br. J. Pharmacol.</i> 134(1):58-67 (2001)	
	106	SELDON et al., "Interleukin-10 Does Not Mediate the Inhibitory Effect of PDE-4 Inhibitors and Other cAMP-Elevating Drugs on Lipopolysaccharide-Induced Tumors Necrosis Factor- α Generation from Human Peripheral Blood Monocytes," <i>Cell Biochem. Biophys.</i> 29(1-2):179-201 (1998)	
	107	SMYTH et al., "Unlocking the Secrets of Cytotoxic Granule Proteins," <i>J. Leukoc. Biol.</i> 70(1):18-29 (2001)	
	108	SOMMER et al., "Therapeutic Potential of Phosphodiesterase Type 4 Inhibition in Chronic Autoimmune Demyelinating Disease," <i>Journal of Neuroimmunology</i> 79:54-61 (1997)	
	109	SOUZA et al., "Effects of Inhibition of PDE4 and TNF- α on Local and Remote Injuries Following Ischaemia and Reperfusion Injury," <i>Br. J. Pharmacol.</i> 134(5):985-994 (2001)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known		
				Application Number		10/532,291
				Filing Date		October 21, 2003
				First Named Inventor		Rodney William Kelly
				Group Art Unit		To Be Assigned
				Examiner Name		To Be Assigned
Sheet	9	of	9	Attorney Docket Number		20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	110	STAFFORD & FELDMAN, "Chapter 8. Chronic Pulmonary Inflammation and Other Therapeutic Applications of PDE IV Inhibitors," <i>Annual Reports in Medicinal Chemistry</i> , Ed. Bristol, Academic Press, NY, USA, 31:71-80 (1996)	✓
	111	STEINBRINK et al., "Induction of Dendritic Cell Maturation and Modulation of Dendritic Cell-Induced Immune Responses by Prostaglandins," <i>Arch. Dermatol. Res.</i> 292(9):437-445 (2000)	✓
	112	STEINBRINK et al., "Induction of Tolerance by IL-10-Treated Dendritic Cells," <i>J. Immunol.</i> 159(10):4772-4780 (1997)	✓
	113	STRASSMAN et al., "Evidence for the Involvement of Interleukin 10 in the Differential Deactivation of Murine Peritoneal Macrophages by Prostaglandin E ₂ ," <i>J. Exp. Med.</i> 180:2365-2370 (1994)	✓
	114	TEIXEIRA et al., "Phosphodiesterase (PDE)4 Inhibitors: Anti-Inflammatory Drugs of the Future?" <i>Trends Pharmacol. Sci.</i> 18:164-171 (1997)	✓
	115	UNDERWOOD et al., "The Influence of Endogenous Catecholamines on the Inhibitory Effects of Rolipram Against Early- and Late-Phase Response to Antigen in the Guinea Pig," <i>Journal of Pharmacology and Experimental Therapeutics</i> 280(1):210-219 (1997)	✓
	116	VAN DER POUW KRAAN et al., "Prostaglandin-E2 Is a Potent Inhibitor of Human Interleukin 12 Production," <i>J. Exp. Med.</i> 181(2):775-779 (1995)	✓
	117	VAN DER POUW KRAAN et al., "Regulation of IL-12 Production by Human Monocytes and the Influence of Prostaglandin E ₂ ," <i>Annals of the New York Academy of Sciences</i> 795:147-157 (1996)	✓
	118	WANG et al., "Phosphodiesterase 4B2 Is The Predominant Phosphodiesterase Species and Undergoes Differential Regulation of Gene Expression in Human Monocytes and Neutrophils," <i>Mol. Pharmacol.</i> 56(1):170-174 (1997)	✓
	119	WONG et al., "Human GM-CSF: Molecular Cloning of the Complementary DNA and Purification of the Natural and Recombinant Proteins," <i>Science</i> 228(4701):810-815 (1985)	✓
	120	ZEINEDDINE et al., "Macrophages that Kill Glioma Cells Expressing the Membrane Form of Macrophage Colony Stimulating Factor Are Resistant to Prostaglandin E2 and Interleukin-10," <i>Immunol. Lett.</i> 70(1):63-68 (1999)	✓

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Art Unit	To Be Assigned
Examiner Name	To Be Assigned				
Sheet	1	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	1	US-4,034,087	07/05/1977	Voorhees	
	2	US-4,127,612	11/28/1978	Kluender et al.	
	3	US-5,229,496	07/20/1993	Deeley et al.	
	4	US-5,391,485	02/21/1995	Deeley et al.	
	5	US-5,393,870	02/28/1995	Deeley et al.	
	6	US-5,602,007	02/11/1997	Dunn et al.	
	7	US-5,891,432	04/06/1999	Hoo	
	8	US-5,908,829	06/01/1999	Kelly	
	9	US-6,010,905	01/04/2000	Cohen et al.	
	10	US-6,127,378	10/03/2000	Gutterer	
	11	US-6,280,718 B1	08/28/2001	Kaufman et al.	
	12	US-6,458,585 B1	10/01/2002	Vachula et al.	
	13	US-6,458,589 B1	10/01/2002	Rambhatla et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	14	DE 100 64 991 A1	06/27/2002	Volker		X
	15	DE 24 31 558	01/23/1975	Kuehl jun et al.		X
	16	EP 0 269 017 B1	07/29/1992	Zimmermann et al.		
	17	EP 1 097 922 A1	05/09/2001	Maruyama et al.		
	18	EP 1 114 816 A1	07/11/2001	Maruyama et al.		
	19	EP 1 199 074 A1	04/24/2002	Moulon et al.		
	20	JP 10-29942	02/03/1998	Tadahiro et al.		X
	21	WO 00/64260	11/02/2000	Benoit et al.		
	22	WO 01/17479 A2	03/15/2001	Neal		
	23	WO 02/092064 A2	11/21/2002	Kelly		
	24	WO 91/06571	05/16/1991	Geffer et al.		
	25	WO 92/08474	05/29/1992	Kay et al.		
	26	WO 94/24281	10/27/1994	Garman et al.		
	27	WO 96/30022	10/03/1996	Desai et al.		
	28	WO 99/12563	03/18/1999	Berzofsky et al.		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at 222.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	2	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	29	"Leukine®," Package Insert, Approved Text (February 1998)	
	30	ALGHAFEER & SIGAL, "Rheumatic Manifestations of Gastrointestinal Diseases," <i>Bulletin on the Rheumatic Diseases</i> 51(2):1-7 (Retrieved from the internet at http://www.arthritis.org/research/bulletin/vol51no2/51_2_printable.asp) (March 10, 2005)	
	31	ASANUMA et al., "Successful Treatment of Interstitial Pneumonia with Lipo-PGE1 and Pentoxifylline in a Patient with Dermatomyositis," <i>Ryumachi</i> 37(5):719-726 (1997) (English language abstract only)	
	32	ASSEMAN et al., "Interleukin 10 is a Growth Factor for a Population of Regulatory T Cells," <i>Gut</i> 42(2):157-158 (1998)	
	33	AITKEN et al., "Significance of Intracellular Calcium and Cyclic Adenosine 3',5'-monophosphate in the Mechanisms by Which Prostaglandins Influence Human Sperm Function," <i>J. Reprod. Fert.</i> 77:451-462 (1986)	
	34	BELL, J., "Transplantation: Privileged Beginnings," <i>Nature Reviews Immunology</i> 2:75 (2002)	
	35	BERENDS et al., "Inhibitions of PAF-Induced Expression of CD11b and Shedding of L-Selectin on Human Neutrophils and Eosinophils by the Type IV Selective PDE Inhibitor, Rolipram," <i>Eur. Respir. J.</i> 10:1000-1007 (1997)	
	36	BRAUN et al., "Cholera Toxin Suppresses Interleukin (IL)-12 Production and IL-12 Receptor β 1 and β 2 Chain Expression," <i>J. Exp. Med.</i> 189(3):541-552 (1999)	
	37	BRODSKY et al., "Forskolin Induces U937 Cell Line Differentiation as a Result of a Sustained cAMP Elevation," <i>Eur. J. Pharmacol.</i> 350(1):121-127 (1998)	
	38	BUCHSEL et al., "Granulocyte Macrophage Colony-Stimulating Factor: Current Practice and Novel Approaches," <i>Clin. J. Oncol. Nurs.</i> 6(4):198-205 (2002)	
	39	BUG et al., "cAMP Analogues Downregulate the Expression of Granulocyte Macrophage Colony-Stimulating Factor (GM-CSF) in Human Bone Marrow Stromal Cells <i>In Vitro</i> ," <i>Mediators of Inflammation</i> 7:195-199 (1998)	
	40	BURZYN et al., "Decrease in cAMP Levels Modulates Adhesion to Fibronectin and Immunostimulatory Ability of Human Dendritic Cells," <i>J. Leukoc. Biol.</i> 72:93-100 (2002)	

Examiner Signature	Date Considered
--------------------	-----------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	3	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	41	CANTRELL et al., "Cloning, Sequence, and Expression of a Human Granulocyte/Macrophage Colony-Stimulating Factor," <i>Proc. Natl. Acad. Sci. USA</i> 82(18):6250-6254 (1985)		
	42	CLAESSEN et al., "Reversal of Mucosal Tolerance by Subcutaneous Administration of Interleukin-12 at the Site of Attempted Sensitization," <i>Immunology</i> 88(3):363-367 (1996)		
	43	CROCKER et al., "Phosphodiesterase Type 4 Inhibitors, But Not Glucocorticoids, Are More Potent in Suppression of Cytokine Secretion by Mononuclear Cells from Atopic Than Nonatopic Donors," <i>J. Allergy Clin. Immunol.</i> 102(5):797-804 (1998)		
	44	DIECKGRAEFE & KORZENIK, "Treatment of Active Crohn's Disease with Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor," <i>The Lancet</i> 360:1478-1480 (2002)		
	45	DONCKIER et al., "IL-12 Prevents Neonatal Induction of Transplantation Tolerance in Mice," <i>Eur. J. Immunol.</i> 28(4):1426-1430 (1998)		
	46	DOUSA, T.P., "Cyclic-3', 5'-Nucleotide Phosphodiesterase Isozymes in Cell Biology and Pathophysiology of the Kidney," <i>Kidney International</i> 55:29-62 (1999)		
	47	DRUKKER et al., "Characterization of the Expression of MHC Proteins in Human Embryonic Stem Cells," <i>Proc. Natl. Acad. Sci. USA</i> 99(15):9864-9869 (2002)		
	48	DUNN et al., "IL-15 Regulation in Human Endometrial Stromal Cells," <i>J. Clin. Endocrinol. Metab.</i> 87(4):1898-1901 (2002)		
	49	ESCOFIER et al., "Effects of Interleukin-10 and Modulators of Cyclic AMP Formation on Endotoxin-Induced Inflammation in Rat Lung," <i>Fundam. Clin. Pharmacol.</i> 13(1):96-101 (1999)		
	50	GASPAR ELSAS et al., "Murine Myeloid Progenitor Responses to GM-CSF and Eosinophil Precursor Responses to IL-5 Represent Distinct Targets for Downmodulation by Prostaglandin E ₂ ," <i>Br. J. Pharmacol.</i> 130(6):1362-1368 (2000)		
	51	GENBANK ACCESSION NO. NM_000758 (2002)		
	52	GOERDT et al., "Other Functions, Other Genes: Alternative Activation of Antigen-Presenting Cells," <i>Immunity</i> 10:137-142 (1999)		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	4	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	53	GROUX et al., "Interleukin-10 Induces a Long-Term Antigen-Specific Anergic State in Human CD4 ⁺ T Cells," <i>J. Exp. Med.</i> 184:19-29 (1996)	
	54	GROUX et al., "A CD4 ⁺ T-Cell Subset Inhibits Antigen-Specific T-Cell Responses and Prevents Colitis," <i>Nature</i> 389:737-742 (1997)	
	55	HAMILTON, J.A., "GM-CSF in Inflammation and Autoimmunity," <i>Trends Immunol.</i> 23(8):403-408 (2002)	
	56	HANCOCK et al., "Recombinant Granulocyte-Macrophage Colony-Stimulating Factor Down-Regulates Expression of IL-2 Receptor on Human Mononuclear Phagocytes by Induction of Prostaglandine," <i>J. Immunol.</i> 140(9):3021-3025 (1988)	
	57	HANIFIN & CHAN, "Monocyte Phosphodiesterase Abnormalities and Dysregulation of Lymphocyte Function in Atopic Dermatitis," <i>J. Invest. Dermatol.</i> 105:84S-88S (1995)	
	58	HANIFIN et al., "Type 4 Phosphodiesterase Inhibitors Have Clinical and <i>In Vitro</i> Anti-Inflammatory Effects in Atopic Dermatitis," <i>Journal of Investigative Dermatology</i> 107:51-56 (1996)	
	59	HARIZI et al., "Cyclooxygenase-2-Issued Prostaglandin E ₂ Enhances the Production of Endogenous IL-10, Which Down-Regulates Dendritic Cell Functions," <i>J. Immunol.</i> 168(5):2255-2263 (2002)	
	60	HASKÓ et al., "Suppression of IL-12 Production by Phosphodiesterase Inhibition in Murine Endotoxemia is IL-10 Independent," <i>Eur. J. Immunol.</i> 28:468-472 (1998)	
	61	HATA et al., "Granulysin Blocks Replication of Varicella-Zoster Virus and Triggers Apoptosis of Infected Cells," <i>Viral Immunol.</i> 14(2):125-133 (2001)	
	62	HAYASHIDA et al., "Antiinflammatory Effects of Colforsin Daropate Hydrochloride, a Novel Water-Soluble Forskolin Derivative," <i>Ann. Thoracic Surgery</i> 71:1931-1938 (2001)	
	63	HOLT et al., "MHC Class II Antigen-Bearing Dendritic Cells in Pulmonary Tissues of the Rat," <i>J. Exp. Med.</i> 167:262-274 (1988)	
	64	ICHIMURA et al., "Differentiation of a Cell Line of Human Cervical Argyrophil Small Cell Carcinoma to Macrophage Lineage Cells," <i>Jpn. J. Cancer Res.</i> 90:523-529 (1999)	

Examiner Signature	Date Considered
--------------------	-----------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	5	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	65	KALIŃSKI et al., "Dendritic Cells, Obtained from Peripheral Blood Precursors in the Presence of PGE ₂ , Promote Th2 Responses," <i>Adv. Exp. Med. Biol.</i> 416:363-367 (1997)	
	66	KALIŃSKI et al., "Final Maturation of Dendritic Cells Is Associated with Impaired Responsiveness to IFN- γ and to Bacterial IL-12 Inducers: Decreased Ability of Mature Dendritic Cells to Produce IL-12 During the Interaction with Th Cells," <i>J. Immunol.</i> 162:3231-3236 (1999)	
	67	KALIŃSKI et al., "Prostaglandin E ₂ Induces the Final Maturation of IL-12-Deficient CD1a ⁺ CD83 ⁺ Dendritic Cells: The Levels of IL-12 Are Determined During the Final Dendritic Cell Maturation and Are Resistant to Further Modulation," <i>J. Immunol.</i> 161:2804-2809 (1998)	
	68	KAMBAYASHI et al., "Cyclic Nucleotide Phosphodiesterase Type IV Participates in the Regulation of IL-10 and in the Subsequent Inhibition of TNF- α and IL-6 Release by Endotoxin-Stimulated Macrophages," <i>Journal of Immunology</i> 155:4909-4916 (1995)	
	69	KANAMORI et al., "Migration of Neutrophils from Blood to Tissue: Alteration of Modulatory Effects of Prostanoid on Superoxide Generation in Rabbits and Humans," <i>Life Science</i> 60(16):1407-1417 (1997)	
	70	KANDA & WATANABE, "Ganglioside GD1a Enhances Immunoglobulin Production by Human Peripheral Blood Mononuclear Cells," <i>Exp. Hematol.</i> 28(6):672-679 (2000)	
	71	KELLY & CRITCHLEY, "Immunomodulation by Human Seminal Plasma: A Benefit for Spermatozoon and Pathogen?" <i>Human Reproduction</i> 12(10):220-2207 (1997)	
	72	KELLY et al., "Inflammatory Mediators and Endometrial Function—Focus on the Perivascular Cell," <i>J. Reprod. Immunol.</i> 57(1-2):81-93 (2002)	
	73	KELLY, J., "Shooting for the Moon: Bolstered By a New Research Agenda, Parkinson's Disease Researchers Aim High," <i>Neurology Reviews.com</i> 9(7):1-10 (2001)	
	74	KELLY et al., "The Immunosuppressive Contribution of Prostaglandin Components of Human Semen and Their Ability to Elevate Cyclic Adenosine Monophosphate Levels in Peripheral Blood Mononuclear Cells," <i>J. Reprod. Immunol.</i> 26:31-40 (1994)	
	75	KOELMAN et al., "Correlation Between Oral Sex and a Low Incidence of Preeclampsia: A Role for Soluble HLA in Seminal Fluid?" <i>J. Reproductive Immunol.</i> 46:155-166 (2000)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	
				10/532,291	
				Filing Date	
				October 21, 2003	
				First Named Inventor	
Rodney William Kelly					
Group Art Unit		To Be Assigned			
Examiner Name		To Be Assigned			
Sheet	6	of	9	Attorney Docket Number	
				20747/280 (ARDBW/P29385US)	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	76	KRENSKY, A.M., "A Novel Antimicrobial Peptide of Cytolytic T Lymphocytes and Natural Killer Cells," <i>Biochem. Pharmacol.</i> 59(4):317-320 (2000)	
	77	LECHNER et al., "Nestin-Positive Progenitor Cells Derived from Adult Human Pancreatic Islets of Langerhans Contain Side Population (SP) Cells Defined by Expression of the ABCG2 (BCRP1) ATP-Binding Cassette Transporter," <i>Biochem. Biophys. Res. Comm.</i> 293:670-674 (2002)	
	78	LEE et al., "Isolation of cDNA for a Human Granulocyte-Macrophage Colony-Stimulating Factor by Functional Expression in Mammalian Cells," <i>Proc. Natl. Acad. Sci. USA</i> 82:4360-4364 (1985)	
	79	LOUIS et al., "Decrease in Systemic Tolerance to Fed Ovalbumin in Indomethacin-Treated Mice," <i>International Archives of Allergy and Immunology</i> 109(1):21-26 (1996)	
	80	MAIER et al., "Unique Molecular Surface Features of <i>in vivo</i> Tolerized T Cells," <i>Proc. Natl. Acad. Sci. USA</i> 95:4499-4503 (1998)	
	81	MAURANO et al., "Intranasal Administration of One Alpha Gliadin Can Downregulate the Immune Response to Whole Gliadin in Mice," <i>Scand. J. Immunol.</i> 53:290-295 (2001)	
	82	MIYATAKE et al., "Structure of the Chromosomal Gene for Granulocyte-Macrophage Colony Stimulating Factor: Comparison of the Mouse and Human Genes," <i>EMBO J.</i> 4(10):2561-2568 (1985)	
	83	MORIUCHI et al., "Synergistic Inhibition of Pannus Tissue Development In Vitro by PGE1 Plus Phosphodiesterase 4 Inhibitors," <i>Arthritis and Rheumatism</i> 41(9):S161 (1998)	
	84	MÜLLER et al., "IL-12 as Mediator and Adjuvant for the Induction of Contact Sensitivity In Vivo," <i>J. Immunol.</i> 155(10):4661-4668 (1995)	
	85	MÜLLER et al., "Subtypes of the Type 4 cAMP Phosphodiesterases: Structure, Regulation and Selective Inhibition," <i>Trends Pharmacol. Sci.</i> 17:294-298 (1996)	
	86	NÉMETH et al., "Amrinone and Theophylline Differentially Regulate Cytokine and Nitric Oxide Production in Endotoxemic Mice," <i>Shock</i> 7(5):371-375 (1997)	
	87	NEWBERRY et al., "Cyclooxygenase-2-Dependent Arachidonic Acid Metabolites Are Essential Modulators of the Intestinal Immune Response to Dietary Antigen," <i>Nature Medicine</i> 5(8):900-906 (1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	7	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	88	NEWBERRY et al., "Spontaneous and Continuous Cyclooxygenase-2-Dependent Prostaglandin E ₂ Production by Stromal Cells in the Murine Small Intestine Lamina Propria: Directing the Tone of the Intestinal Immune Response," <i>J. Immunol.</i> 166(7):4465-4472 (2001)	
	89	NINNEMANN, J.L., "Monocytes and Macrophages," in <i>Prostaglandins, Leukotrienes, and the Immune Response</i> , Chapter 3, pp.34-52 (1988)	
	90	OCHOA et al., "T-Cell Release of Granulysin Contributes to Host Defense in Leprosy," <i>Nature Medicine</i> 7(2):174-179 (2001)	
	91	PALFREYMAN & SOUNESS, "Phosphodiesterase Type IV Inhibitors," <i>Progress in Medicinal Chemistry</i> 33:1-52 (1996)	
	92	PFENDLER & KAWASE et al., "The Potential of Stem Cells," <i>Obstetrical & Gynecology Survey</i> 58(3):197-208 (2003)	
	93	PIQUET-PELLORCE et al., "Prostaglandin E ₂ Potentiates Granulocyte-Macrophage Colony Stimulating Factor-Induced Histamine Synthesis in Bone Marrow Cells: Role of cAMP," <i>Life Sciences</i> 48(25):2377-2385 (1991)	
	94	RIESER et al., "Prostaglandin E ₂ and Tumor Necrosis Factor α Cooperate to Activate Human Dendritic Cells: Synergistic Activation of Interleukin 12 Production," <i>J. Exp. Med.</i> 186(9):1603-1608 (1997)	
	95	RITZ et al., "On the Generation of Allergic Airway Diseases: From GM-CSF to Kyoto," <i>Trends Immunol.</i> 23(8):396-402 (2002)	
	96	ROBERTSON & SHARKEY, "The Role of Semen in Induction of Maternal Immune Tolerance to Pregnancy," <i>Seminars in Immunology</i> 13:243-254 (2001)	
	97	ROBERTSON et al., "Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) Targets Myeloid Leukocytes in the Uterus During the Post-Mating Inflammatory Response in Mice," <i>J. Reproductive Immunology</i> 46:131-154 (2000)	
	98	ROWE et al., "Inability of Histamine to Regulate TNF- α Production by Human Alveolar Macrophages," <i>Am. J. Respir. Cell Mol. Biol.</i> 17:218-226 (1997)	
	99	ROZENGURT et al., "Mitogenic Effect of Prostaglandin E ₁ in Swiss 3T3 Cells: Role of Cyclic AMP," <i>Journal of Cellular Physiology</i> 116:379-384 (1983)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/532,291
				Filing Date	October 21, 2003
				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	8	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	100	RUGTVEIT et al., "Differential Distribution of B7.1 (CD80) and B7.2 (CD86) Costimulatory Molecules on Mucosal Macrophage Subsets in Human Inflammatory Bowel Disease (IBD)," <i>Clin. Exp. Immunol.</i> 110(1):104-113(1997)	
	101	SALMI & JALKANEN et al., "Human Leukocyte Subpopulations from Inflamed Gut Bind to Joint Vasculature Using Distinct Sets of Adhesion Molecules," <i>Journal of Immunology</i> 166(7):4650-4657 (2001)	
	102	SANTAMARIA et al., "Rolipram Inhibits Staphylococcal Enterotoxin B-Mediated Induction of the Human Skin-Homing Receptor on T Lymphocytes," <i>J. Invest. Dermatol.</i> 113:82-89 (1999)	
	103	SCHEUER et al., "Interference with Tolerance Induction <i>in Vivo</i> by Inhibitors of Prostaglandin Synthesis," <i>Cellular Immunology</i> 104(2):409-418 (1987)	
	104	SCHWACHA et al., "Cyclooxygenase 2-Mediated Suppression of Macrophage Interleukin-12 Production After Thermal Injury," <i>Am. J. Physiol. Cell Physiol.</i> 282(2):263-270 (2002)	
	105	SELDON & GIEMBYCZ et al., "Suppression of Granulocyte/Macrophage Colony-Stimulating Factor Release from Human Monocytes by Cyclic AMP-Elevating Drugs: Role of Interleukin-10," <i>Br. J. Pharmacol.</i> 134(1):58-67 (2001)	
	106	SELDON et al., "Interleukin-10 Does Not Mediate the Inhibitory Effect of PDE-4 Inhibitors and Other cAMP-Elevating Drugs on Lipopolysaccharide-Induced Tumors Necrosis Factor- α Generation from Human Peripheral Blood Monocytes," <i>Cell Biochem. Biophys.</i> 29(1-2):179-201 (1998)	
	107	SMYTH et al., "Unlocking the Secrets of Cytotoxic Granule Proteins," <i>J. Leukoc. Biol.</i> 70(1):18-29 (2001)	
	108	SOMMER et al., "Therapeutic Potential of Phosphodiesterase Type 4 Inhibition in Chronic Autoimmune Demyelinating Disease," <i>Journal of Neuroimmunology</i> 79:54-61 (1997)	
	109	SOUZA et al., "Effects of Inhibition of PDE4 and TNF- α on Local and Remote Injuries Following Ischaemia and Reperfusion Injury," <i>Br. J. Pharmacol.</i> 134(5):985-994 (2001)	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	
				10/532,291	
				Filing Date	
				October 21, 2003	
				First-Named Inventor	
		Rodney William Kelly			
Group Art Unit		To Be Assigned			
Examiner Name		To Be Assigned			
Sheet	9	of	9	Attorney Docket Number	
				20747/280 (ARDBW/P29385US)	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	110	STAFFORD & FELDMAN, "Chapter 8. Chronic Pulmonary Inflammation and Other Therapeutic Applications of PDE IV Inhibitors," <i>Annual Reports in Medicinal Chemistry</i> , Ed. Bristol, Academic Press, NY, USA, 31:71-80 (1996)	
	111	STEINBRINK et al., "Induction of Dendritic Cell Maturation and Modulation of Dendritic Cell-Induced Immune Responses by Prostaglandins," <i>Arch. Dermatol. Res.</i> 292(9):437-445 (2000)	
	112	STEINBRINK et al., "Induction of Tolerance by IL-10-Treated Dendritic Cells," <i>J. Immunol.</i> 159(10):4772-4780 (1997)	
	113	STRASSMAN et al., "Evidence for the Involvement of Interleukin 10 in the Differential Deactivation of Murine Peritoneal Macrophages by Prostaglandin E ₂ ," <i>J. Exp. Med.</i> 180:2365-2370 (1994)	
	114	TEIXEIRA et al., "Phosphodiesterase (PDE)4 Inhibitors: Anti-Inflammatory Drugs of the Future?" <i>Trends Pharmacol. Sci.</i> 18:164-171 (1997)	
	115	UNDERWOOD et al., "The Influence of Endogenous Catecholamines on the Inhibitory Effects of Rolipram Against Early- and Late-Phase Response to Antigen in the Guinea Pig," <i>Journal of Pharmacology and Experimental Therapeutics</i> 280(1):210-219 (1997)	
	116	VAN DER POuw KRAAN et al., "Prostaglandin-E2 Is a Potent Inhibitor of Human Interleukin 12 Production," <i>J. Exp. Med.</i> 181(2):775-779 (1995)	
	117	VAN DER POuw KRAAN et al., "Regulation of IL-12 Production by Human Monocytes and the Influence of Prostaglandin E ₂ ," <i>Annals of the New York Academy of Sciences</i> 795:147-157 (1996)	
	118	WANG et al., "Phosphodiesterase 4B2 Is The Predominant Phosphodiesterase Species and Undergoes Differential Regulation of Gene Expression in Human Monocytes and Neutrophils," <i>Mol. Pharmacol.</i> 56(1):170-174 (1997)	
	119	WONG et al., "Human GM-CSF: Molecular Cloning of the Complementary DNA and Purification of the Natural and Recombinant Proteins," <i>Science</i> 228(4701):810-815 (1985)	
	120	ZEINEDDINE et al., "Macrophages that Kill Glioma Cells Expressing the Membrane Form of Macrophage Colony Stimulating Factor Are Resistant to Prostaglandin E2 and Interleukin-10," <i>Immunol. Lett.</i> 70(1):63-68 (1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.